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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,228	05/26/2000	Pawan Seth	8674-000004	2041

7590 12/08/2003

Harness Dickey & Pierce P L C
P O Box 828
Bloomfield Hills, MI 48303

EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	21

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/583,228	SETH, PAWAN	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-14, 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 October 2003 has been entered.

Applicant's arguments are persuasive to remove the obviousness double patenting rejection in the prior office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-14, 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (USPN 5,378,474).

Morella et al. (USPN 5,378,474) teaches a substantially similar composition as those claimed herein. Morella et al. (USPN 5,378,474) teaches a sustained release pharmaceutical composition having a core element containing an antihypertensive agent such as Verapamil Hydrochloride, a methacrylic polymer (1-30% wt., soluble at a pH from 6-7.5 in the intestines), hydroxypropyl methylcellulose (4-20% wt.), polyethylene glycol (15-35% wt.) and a filler such as silicon dioxide (4-30% wt.), see claims 1, 2, 7 and 9 as well as Col.4, line 24. Morella et al.

(USPN 5,378,474) also teaches that the active ingredient in the pharmaceutical composition reaches its maximum concentration between about 4 and about 30 hours, col. 24, claim 1 and that the bioavailability of the active agents in the pharmaceutical pellet is not compromised by food, col.7, lines 34-40. Morella discloses at least one polymer which is substantially insoluble at acidic pH [i.e., that of the stomach] but at least partially soluble at a less acidic to basic pH [i.e., the pH of the intestine], see col. 6, lines 43-52 col. 7 lines 34-62 in particular.

Morella et al. (USPN 5,378,474) does not teach the particular composition containing the specific ingredients in the amounts herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the particular composition containing the specific ingredients herein in amounts herein.

One of ordinary skill in the art would have been motivated to make the composition claimed herein since a substantially similar composition is taught in the prior art. Morella et al. (USPN 5,378,474) teaches a similar composition which may contain an antihypertensive agent (including verapamil) and the excipients herein in amounts (wt. percentages) that overlap with those in the instant claims. The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. The instant composition is not seen to patentably distinguish over the prior art, absent evidence to the contrary. No such evidence is seen.

Response to Arguments

Applicant's arguments filed 9 October 2003 have been fully considered but they are not persuasive. Applicant first argues that the Morella composition comprising a hybrid core coating

which **must** include a polymer that is insoluble regardless of pH. Note that Morella teaches that its coating **may** include a polymer that is insoluble regardless of pH, see col. 8, lines 38-40 for example.

Applicant further states that Morella teaches a tenary system of polymers. Note that the instant claims do not exclude a tenary system of polymers. The instant claims recite that the polymer component "consists essentially of". Note that the transitional phrase "consists essentially of" only excludes elements that would change the novel and basic characteristics of the invention. Further note that the addition or omission of a polymer does not change the novel and basic characteristics of the invention.

Applicant then states that Morella's coating will begin dissolving in the stomach, and continue to dissolve in the region after the pyloric sphincter, in the small intestine and finally in the large intestine. Note that the instant claims do not recite the dissolution of **the coating in its entirety, i.e., the multi-element polymeric and non-polyemric components**, they simply recite the dissolution of the **gastroresistant polymer**. Note that similar to the instant claims, the composition of Morella is absorbed in the small intestine, see col. 7, lines 51-58 in particular. Further note that Applicant's submitted declaration provides that the in the stomach both compositions (i.e., Morella's as well as the instant claimed composition) behave similarly, see paragraph 9.

Applicant argues that the Skilled Artisan would not have expected the composition of the instant claims to lead to the release of Verapamil without food effects. Note that the Skilled Artisan would have indeed expected the release of Verapamil without food effects because

Morella explicitly teaches that the effect of the active agent, e.g., Verapamil is not compromised by food as discussed in the rejection herein above. Applicant then refers to formulations 1 and 2 of Morella to support this proposition. Note that formulations 1 and 2 have morphine, not verapamil, as an active ingredient. Further note that the teachings of a prior art reference need to be taken as a whole. Throughout the Morella reference, the Skilled Artisan can find that the composition is not compromised by food, see for example, col. 1, lines 35-39, col. 7, lines 34-40 for example.

Applicant finally states that contrary to Applicant's earlier statements, including those filed in the declaration of Dr. Seth filed under 37 CFR 1.132, the bioavailability of Morella is affected by the food intake. Note that the reason for the change in applicant's position is not clear.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
December 4, 2003